Clothing protocol in a Controlled Environment (CE) food production facility?

Summary

Working in a room in which the climate conditions are controlled and the contamination of the air (pollution by dust particles, chemical or micro-biological pollution) is constantly kept at a certain desired level has enormously increased over the past decades. Such Controlled Environment (CE) facilities are often referred to as Cleanrooms in the semiconductor and pharmaceutical sectors. Other sectors also use more specific terms, such as OR (Operating Room) in health care or a Medium/High Care room in the food industry.

A properly designed CE facility by itself, however, is not enough to ward off all risks of contamination! A good cleaning schedule, the right behaviour by well-trained staff and above all, a correct clothing protocol are all determinative factors in achieving satisfying end results.

We realise that it is not possible to thoroughly cover everything in a short essay on such a complex subject as a clothing protocol in a Controlled Environment but we will attempt to make a brief, clear contribution in the best interests of food safety in general. In this White Paper we will come to know more about the effects that humans have as polluters operating in a food production area and we examine how the clothing industry can contribute to achieving a higher level of food safety.

PP4CE
professional partners for controlled environment

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Introduction

The rapid growth in the number of cleanrooms and other CE facilities as mentioned in the summary is largely related to the equally rapid growth of the international semi-conductor market led by a large number of suppliers. In this market, the focus is primarily on the amount of dust particles per m3 according to the ISO 14644 standard or chemical contamination by "outgassing" (volatile organic compounds) which is the collective name for a group of hydrocarbons that, as the name suggests, easily vaporise. These include, for example, components in solvents or plasticisers. The vaporisation process is also sometimes called outgassing.

But also the market in which we focus on combatting micro-biological contamination and cross-contamination is growing steadily. The pharmaceutical, cosmetic and to an ever-increasing extent, the food industry are prime examples and in these markets specific GMP (Good Manufacturing Practices) guidelines apply. We have already covered this GMP legislation in an earlier White Paper.

That White Paper covered the change in requirements for GMP for the food sector in the USA and was downloaded by many people. A few items from that White Paper, compiled in the section below, can offer insight into the latest developments within the food market:

Food safety is becoming an increasingly important subject in the international market. In order to guarantee the safety and quality of our food supply, statutory food safety regulations are being implemented in various parts of the world and guidelines and directives have come into force for the various disciplines in this very important sector (including production, storage and transport).

The international food trade has existed for centuries, but until recently, food was always primarily produced, sold and consumed locally. The world population is growing and mobility is increasing. As a result, a menu, or a home or a restaurant can these days offer a choice of dishes from every corner of the world. No matter where they are in the world, people now want to consume foods which until only a few decades ago, were totally unknown beyond the borders of the country of origin. That is why over the course of the last century, the amount of food traded internationally has grown exponentially. The causes of an ever-increasing number of problems surrounding food safety in relation to this growth are listed below:

- *Growth of the world population*
- *Globalisation results in more international traffic*
- *The food chain is therefore getting longer and longer*
- *Less control over recall actions due to complex distribution*

An analysis of the threatening dangers in the food industry can be divided up into 4 categories. Some are visible or noticeable upon consumption, others are invisible dangers that can have grave consequences for consumers:

1. *Physical and visible contamination such as bone fragments, metal particles, etc.*
2. *Micro-biological contamination such as viruses, fungi and bacteria.*
3. *Chemical contamination from raw materials used (including antibiotics or hormones used in livestock or pesticides used in agriculture).*
4. *Allergens that are not stated on the packaging.*

The beginnings of a management process in which risk analyses form the basis for the measures to be taken as well as for monitoring and registering certain activities within this framework (in principle, the founding of the HACCP) have now been included separately in the GMP.

In addition, the directive describes the food safety system (under supervision) must be compiled and certified by a qualified person: a Preventive Controls Qualified Individual (PCQI) and there is clearly more focus on training all of the employees involved in the production and logistical process.

On 7 June, we celebrated the first ever World Food Safety Day. A day dedicated to the interest of food safety. **Every minute in Europe alone, 44 people get sick or contaminated by food and every day, roughly 13 deaths are recorded due to food safety issues.** This is an unbelievably high number. With World Food Safety Day, the World Health Organization (WHO) wants to generate more awareness for this major problem.

A 10-year international study initiated by the WHO in 2005 yielded alarming results which were still labelled as conservative estimates:

- 600 million cases of transferred diseases due to food safety problems
- 420,000 deaths, of which 125,000 children < age 5 due to food safety problems

For more information on this shocking report we refer you to its content via the link. https://apps.who.int/iris/bitstream/handle/10665/200046/WHO_FOS_15.02_eng.pdf?sequence=1

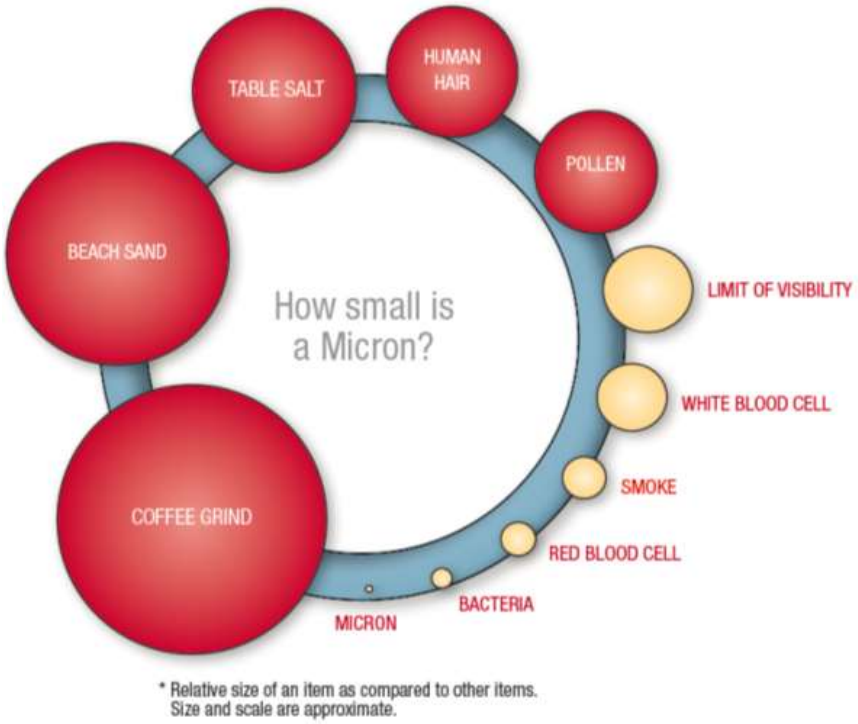
Based on the above facts, it can be expected that legislation concerning food safety will become more and more stringent and enforcement more intense.

The people in a CE facility!

Food safety problems can be caused by a whole host of problems. Insufficient hygiene, amongst others, especially at the point where the food contacts a contaminated surface. Human failure or procedural problems that play an important role in the process of protecting food from micro-biological contamination as a result of after-contamination, re-contamination or a cross-contamination that can lead to food safety problems. But also micro-biological contamination due to incorrect storage (temperatures), vermin or exposure to micro-biological contamination from outside can often lead to safety problems.

To reduce human failure during the production process, established and agreed Standard Operating Procedures (SOP) are used as often as possible to ensure that everyone behaves and acts in accordance with the agreements made and on the basis of best experience and knowledge. All of these procedural measures and working methods are usually developed in Europe as based on the General Food Law and a statutorily required HACCP principle. These letters stand for Hazard Analysis Critical Control Points and the HACCP process and the results are comparable to a risk assessment process.

A big contamination problem can also, however, be caused by the people themselves who are active in the room! We can establish that this concerns contamination due to dust particles with or without a micro-biological contamination already present, which can often be 0.4 to 0.8 micron in size. To clarify again: a human hair is approx. 70 micron thick in diameter. One micron is just a fraction of this...



People are often stunned when you reveal how many dust particles are caused by humans themselves. Even when standing still, humans spread an incredible number of dust particles of various sizes. The overview below indicates how much contamination a human causes with certain movements:

	Standing	Walking	Standing	Walking	Standing	Walking
Clothing	**> 0.5 micron**	**> 0.5 micron**	**> 1 micron**	**> 1 micron**	**> 5 micron**	**> 5 micron**
Jogging outfit	850,000	35,000,000	650,000	25,000,000	17,000	450,000
Work coat	330,000	6,300,000	130,000	2,500,000	10,000	100,000
Coverall	28,000	110,000	10,000	30,000	330	850

Particle distribution per minute with various activities and clothing

It is not the fine particles themselves that can cause problems but primarily the micro-organisms that these fine particles carry. The human body is a complicated system that houses billions of microbial cells over the epithelial (skin) surface, in the mouth and in the intestine. These micro-organisms play a role in human physiology and organ function, including digestion and immunity. The micro-organisms also have an influence on the exterior environment because they are divested from the skin or repelled via various openings. This last problem has significant implications for Controlled Environment facilities in the pharmaceutical, medical and also the food sector. Please note: The human skin can contain 1 to 20 million micro-organisms per square centimetre!

AREA	NUMBER OF MICRO-ORGANISMS / cm^2	UNIT
Scalp	1,000,000	cm^2
Saliva and nasal fluid	10 million	grams
The back	100	cm^2
The groin	1 - 20 million	cm^2
Forehead	100-1000	cm^2
Hand	10,000 - 100,000	cm^2
Armpit	1-10 million	cm^2
Feet	1,000,000	cm^2

Places on the human body and the quantity of micro-organisms within that environment

Humans also release elementary chemicals that can cause contamination:

- Saliva: potassium, chloride, phosphorous, magnesium and sodium.
- Dandruff: calcium, chloride, carbon and nitrogen.
- Sweat: sodium, potassium, chloride, sulphur, aluminium, carbon and nitrogen.
- Fingerprints: sodium, potassium, chloride and phosphorous.

It goes without saying that a good clothing protocol will be vital in the food sector in a general sense, and inside high-risk locations, the so-called “High Care” rooms, it will be especially important.

What are the requirements?

The hygienic code of conduct and the use of production attire within the food production or food research facility, in the broadest sense of the word, are described in the GMP FOOD CFR - section 110:

(b) Cleanliness:

All persons who come into direct contact with food, food-contact surfaces or food packaging materials, must adhere to the hygienic work procedures during the shift for the benefit of protecting the food against contamination.

The work procedures to maintain cleanliness are comprised of, but not limited to the following:

(1) Wear suitable top clothing that is suitable for work so that food, food packaging materials as well as food-contact surfaces are protected against contamination.
(2) Maintain sufficient personal hygiene
(3) Wash hands thoroughly (and disinfect if necessary to protect against contamination by undesired micro-organisms) in a suitable hand-washing facility before you commence work, after any absence from the work station and at any other moment that the hands can possibly be contaminated.
(4) The removal of all loose jewellery and other objects that could fall into the food, equipment or containers, and the removal of hand jewellery that cannot be sufficiently cleaned during periods in which food is manipulated by the hands. If such hand jewellery cannot be removed, it should be covered with a material that is in an intact, clean and hygienic state and effectively protects against contamination from these objects of the food-contact surfaces or food packaging materials.
(5) Keep gloves, if these are used for working with foodstuffs, in an intact, hygienic and completely clean state. The gloves must be made of an impenetrable material.
(6) Whenever necessary, wear hair nets, head bands, hats, beard covers and other hair covers in an effective manner.
(7) Store clothing and other personal items in other areas than where food is exposed or where equipment and utensils are washed.
(8) Only eat food, chew gum, drink or smoke in the specifically designated appropriate areas.
(9) Take all the other necessary precautionary measures to prevent contamination of food, food packaging materials as well as food-contact surfaces with micro-organisms or foreign

substances, including but not limited to, perspiration, hair, cosmetics, chemicals, and medicines used on the skin.

(c) Education and training:
Personnel that are responsible for the identification of malfunctions in the sanitary facilities or food contamination must have a background that includes education or experience, or a combination thereof, in order to provide a competency level that is required for the production of clean and safe food. Food processors and supervisors must be given proper training in the right techniques for handling food and food protection principles and must be informed about the dangers of bad personal hygiene and practices.

(d) Supervision:
The responsibility for safeguarding compliance by all staff members to all requirements of this aspect must clearly be assigned to authorised supervisory personnel.

The rapidly growing RTE market

The Ready-To-Eat market is expected to grow considerably in the coming years. Eating away from home, snacks on the road, whether it is with family or friends or with business relations, this market is growing rapidly. And even when we eat at home after work or school, we spend less time in the kitchen than our parents did.
Buying a sandwich or other snack has become a standard routine for the modern office worker. For dinner we pick up a frozen vacuum-packed pizza or lasagna along the way or even a complete meal.

Another variation that is growing quickly is the home-delivered meal boxes that have all the ingredients which only need to be prepared. Not a real RTE variation but a development in the food market which requires more human handling of food during the complete production process.

All of these meals are produced, compiled and/or packaged by hands. The production of RTE meals is thereby extra vulnerable to contamination. The human skin and clothing are risks as discussed earlier for the transfer of bacteria, fungi and yeasts. Are you sure that the nice boy or girl who prepares your sandwich has properly washed and disinfected their hands after a visit to the toilet? Or after they left their home and cuddled their favourite pet?

The many available options...

In order to determine how you will put a correct clothing protocol into practice that will be accepted by all involved and complies with the technical requirements and economic considerations, there are a number of aspects to take into account and discuss. Consider determining the clothing protocol as a collective project and be sure to update it every year and maintain a support base among the personnel.

Many questions must be answered in order to satisfy all parties involved. That is why we recommend that you determine the clothing protocol and make choices as a team. It goes without saying that production management, QA and QC Managers, production staff delegates and other possible involved parties first sit down to discuss the requirements that the clothing must fulfil from a technical perspective. These technical perspectives must be related to and based on a proper risk inventory. (HACCP)
The clothing protocol must be divided according to the given risk classification and must meet the related requirements.
Low, Medium and High Care facilities require their own bespoke and specific approach. The type of production process is also largely determinative, of course. This includes various processes, (wet or dry), temperature conditions, degree of automation and the switch/change frequency.

Cleanroom class	ISO 7 / 8	ISO 6	ISO 5	ISO 5 for Aseptic	ISO 4	ISO 3	ISO 1 / 2
Frequency of Change	2 per week	3 per week	Daily	Per entry	Per entry	Per entry	Per entry

Source: IEST – RP – CC003.4

The choice between having disposable clothing or clothing that requires cleaning is not only related to the quantities. It is in any case necessary to establish whether the cleanliness of disposable clothing deviates from cleaned clothing. Disposable clothing is often manufactured in non-CE facilitated production locations. Contamination that takes place at these locations as a result of this shall end up in your production; this could include dust particles that may or may not be contaminated with bacteria and viruses. In other work environments, however, disposable clothing can be necessary because cleaning is not possible due to the composition of possibly hazardous contamination.

Choice of materials and model must be made and is in any event quite important when users know which requirements the clothing must meet. It is usually your supplier who can furnish the best advice as based on the known production qualities. In some cases, it will be necessary

to develop a material that meets highly specific requirements. In the food sector, however, this is less common at a client level. There are often specific design needs. Here, you must pay attention to storage compartments in the clothing in the form of pockets which can be placed where dust collects and are difficult to clean! Simplicity is often the best motto!

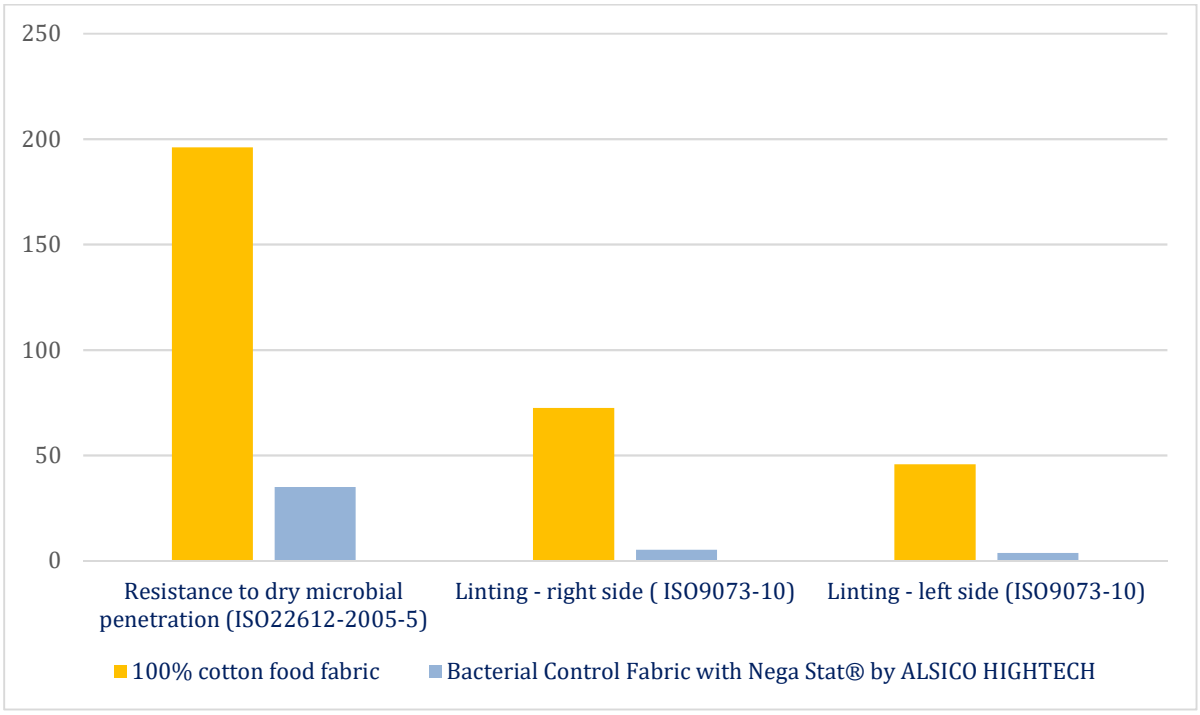
Note: most suppliers primarily offer a cleaning service and the logistical concept. These are very important aspects for you as client! Support in the design and choice of materials is often, however, handled by a specialised firm and in most cases, by the clothing manufacturer itself. If your company is internationally active then it is equally important to find a reliable (supply of suitable clothing) partner who can also deliver globally. Cleaning and logistical services can take place locally, the identical application of the specific materials and models at the various international locations must, however, be guaranteed by the clothing manufacturer!

Bacterial Control Garments by Alsico Hightech

Clothing items can clearly reduce the release and transfer of bacteria that are carried over by people and the clothing they wear.
The objective is to reduce the amount of bacterial transfer to the food product during processing, and considering the potential desired shelf-life, to reduce the bacterial risk and offer better quality assurance.

Although we usually do not mention a specific product or service in a White Paper, we will make an exception for the following innovative development. The Bacterial Control Garments concept offers specific benefits for the food industry that you need to know about. The Alsico Hightech assortment of “bacterial control clothing” is an innovative development that offers a high degree of barrier protection against the transfer of skin particles and bacteria via the wearer. This product is offered under the brand name of Bacterial Control Garments by Alsico Hightech. This Alsico Hightech collection is on the market under the name “Bacterial Control Garments”.

The bacterial control clothing with a Nega-Stat® thread woven into the fabric in a certain pattern control and reduce the spread of bacteria by the employee and his/her clothing on the “Food-contact surface” (FCS) and the food.
Bacterial control clothing by Alsico Hightech offers a 5x better barrier against the transfer of bacteria and 13x better protection against the spread of particles.
In the summary below, a clear difference can be seen in the uptake of bacterial contamination and the penetration of bacteria into the fabric when compared to 100% cotton fabric.



Hohenstein Institute Gmbh Report 17.8.1.1066

Conclusion:

The cleaning and conditioning of air in a High Risk facility, for example, is highly important in the context of food safety. But, this aspect does not stand alone! Food safety can only be assured with a properly functioning combination of key disciplines. A correctly designed hygienic factory with good cleaning guidelines and the correct conduct by employees as well as a correctly implemented clothing protocol for the desired combination of elementary disciplines in the management of a CE facility, whether it concerns a pharmaceutical, semi-conductor or food company.

ORIGIN

PP4C (Professional Partners for Cleanrooms) is a strategic alliance between a number of specialised firms. These firms are active in the design, construction and maintenance of cleanrooms and laboratories in a broad spectrum of market segments. PP4C is also active in the medium and high care areas in the food industry.

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In collaboration with: **Johan Gevers, Key Account Manager of ALSICO Hightech**

Geerd is the initiator of the PP4C organisation and as also the General Manager of Brecon International B.V., and as such, is strategically involved in the PP4C alliance.
For more information, please visit: http: /www.pp4c.nl

Alsico Hightech is part of the globally operating ALSICO Group, responsible for the development, production and sales of Controlled Environment clothing. The ALSICO Group is an 85 year-old Belgian enterprise, by now managed by the 4th generation and shall shortly reach the € 300 million annual sales mark with approximately 7,500 employees.

For more information, please visit www.alsicohightech.com or www.pp4ce.com